

EXHIBIT P



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,491	08/07/2001	Ravi Chandran	RLL-200US	7002


7590 07/03/2002
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EXAMINER
COOK, REBECCA

ART UNIT	PAPER NUMBER
1614	7

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/923,491	Applicant(s) Chandran et al	
	Examiner Rebecca Cook	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-50 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-50 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4,5,6 6) ☐ Other:

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not received The disclosure is objected to because of the following informalities: page 19 is not centered and text on the right hand side is missing.

Appropriate correction is required.

maint The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: no support is seen in the text for the methods of claims 42 and 43.

Claims 1-7, 33-35, 37-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 the word "association" renders the claim unclear as to its nature. Amending the claims to recite "and a pharmaceutically acceptable liquid carrier" will overcome this rejection.

The recitation "additionally comprises an anti-hyperglycemic agent" in claim 34, 37, 39 is confusing, since metformin is also an anti-hyperglycemic agent.

In claim 42 it is not clear which adverse effects of metformin are reduced.

maint In claim 43 it is not clear how the method facilitates compliance.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

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to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/55320.

'320 (pages 1-4, examples) discloses an oral liquid formulation of claims 1-6, 40-41 for treating diabetes or hyperglycemia comprising metformin or metformin salt; water; a sweetener that does not increase blood glucose and having the properties of further instant dependent claims; and that it may further include disintegrators such as low substituted hydroxymethylcellulose. It further discloses the pH range of further instant dependent claims and pH adjusting agents.

Claim 7 differs over the reference in requiring an alkyl hydroxyethylcellulose. However, in the absence of a showing of unexpected results in Declaration form no unobviousness is seen in an alkyl hydroxyethylcellulose over hydroxymethylcellulose, especially since '320 discloses that other disintegrators may be used.

Claims 42 and 43 differ over the reference in reducing adverse effects of metformin and facilitating compliance. However, it would be obvious to one of ordinary skill in the art that it would be easier to administer a pleasant tasting liquid formulation to a person not able to swallow a tablet than a bitter, salty liquid.

Claims 8-39 and 44-50 differ over the reference in requiring alkyl hydroxyethylcellulose and a polyhydroxy alcohol in specific amounts and that the composition has specific properties.

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Certain claims further require a second anti-hyperglycemic agent. However, it would be obvious to one of ordinary skill to use the additional components in specific amounts having specific properties, since they are well-known agents in the compounding art. Furthermore, no unobviousness is seen in combining two anti-hyperglycemic agents, each of which is known to be useful to treat the same condition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 38-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 3080-1235.


REBECCA COOK
PRIMARY EXAMINER
GROUP 1206 16 14/

July 2, 2002